REMARKS

Amendments

The specification is amended to correct obvious typographical errors. In addition, the name of compound 47 is corrected. The prior correction of the name of compound 47 (Election of May 30, 2006) contained a typographical error. See, e.g., the formula illustrating compound 47 at page 133 and the synthesis of compound 47 in Examples 16.

Claims 25 and 61 are amended to delete "or preventing." Claims 52 and 54 are amended to recite phenyl monosubstituted by acetal. See, e.g., compound 85. Claim 60 is amended to delete duplicate compound names and the incorrect name of compound 47. Claims 86 and 89 are amended to correct claim dependency. Claim 96 is amended to correct an error in dependency. Claim 99 is amended to correct a typographical error and to delete superfluous language. Claim 100 is amended to correct a typographical error. Also, claim 98 is cancelled and new claims 102 and 103 are added. See the structural formulas of compounds 15 and 47 shown at pages 127 and 133 respectively.

Rejection under 35 USC 102(e) in view of Kong et al. (US 6,881,741)

Claims 25, 26, 35, 42, 45-47, 50, 52-56, 58, 59, and 64-67 are rejected as allegedly being anticipated in view of Kong et al. (US '741). This rejection is respectfully traversed.

The Examiner argues that the rejected claims are anticipated in view of compounds 573, 574, and 579 of US '741. Applicants disagree.

Compound 573 of US '741 is 3-[(4-methyl-cyclohexanecarbonyl)-(1-methyl-piperidin-4-yl)-amino]-5-phenyl-thiophene-2-carboxylic acid. In this compound, a piperidinyl group is directly attached to the N atom of the amide group. Compare applicants' group Z. Compound 574 of US '741 is 3-[(4-methyl-cyclohexanecarbonyl)-piperidin-4-yl-amino]-5-phenyl-thiophene-2-carboxylic acid. Here again, a piperidinyl group is directly attached to the N atom of the amide group. Compound 579 of US '741 is 3-[cyclohexyl -(4-methy-cyclohexanecarbonyl-amino]-5-phenyl-thiophene-2-carboxylic acid. In this compound, an unsubstituted cyclohexyl group is directly attached to the N atom of the amide group. Compare applicants' group Z.

It is respectfully submitted that US '741 fails to anticipate applicants' claimed invention. Withdrawal of the rejection is respectfully requested.

Rejection under 35 USC 103(a) in view of Kong et al. (US 6,881,741)

Claims 25, 26, 33, 35, 38-42, 45-47, and 50-101 are rejected as allegedly being obvious in view of Kong et al. (US '741). This rejection is respectfully traversed.

Firstly, as set forth on the cover page, US 6,881,741 is assigned to ViroChem Pharma Inc. The instant application is also assigned to ViroChem Pharma Inc. by virtue of the assignment recorded at reel 016330/ frame 0677. The instant application and US 6,881,741 were, at the time the invention of the instant application was made, owned by Shire BioChem Inc. Both US 6,881,741 and the instant application were then subsequently assigned to ViroChem Pharma Inc. See MPEP 706.02 (l)(2). Withdrawal of the rejection is respectfully requested.

In the rejection, it is first argued that US '741 discloses anticipatory species. However, as discussed above, the species cited by the Examiner do not anticipate the claimed invention. Further, the Examiner argues that US '741 discloses compounds having different substituents attached to the cyclohexyl ring connected to the CO group of the amide structure, citing compounds 409 and 513, or different rings citing compound 509 which has an azepanyl group attached to the N atom of the amide group and a phenyl group attached to the CO group of the amide structure. Neither of these compounds suggests a compound having a group in accordance with applicants' group Z.

With respect to the generic disclosure of US '741, mere disclosure of a broad chemical genus does not render obvious every species encompassed therein. Instead, there must be some motivation that would lead one to select the particular species. In the instant case, no such motivation is presented.

See, e.g., *In re Jones,* 21 USPQ2d 1941, 1943, (Fed. Cir. 1992) wherein the Court in reversing the Board's decision of *prima facie* obviousness, disputed the Board's reliance on the Court's prior decision, *Merck & Co. v. Biocraft Labs, Inc.,* 10 USPQ2d (Fed. Cir. 1989):

> We **decline** to extract from *Merck* the rule that the Solicitor appears to suggest -- that regardless of how broad, a disclosure of a chemical genus renders obvious any species that happens to fall within it. .... In contrast, though Richter [the prior art relied on] discloses the potentially infinite genus of 'substituted ammonium salts' of dicamba, and lists several such salts, the claimed salt here is not specifically disclosed. Nor, as we have explained above, is the claimed salt sufficiently similar in structure to those specifically disclosed in Richter as to render it *prima facie* obvious (emphasis added).

Thus, the analysis used by the Court in *Jones* to determine whether obviousness was established by the prior art was to compare the claimed salt with those salts specifically disclosed by the prior art reference. The specific compounds disclosed by US '741 do not provide motivation to select a compound of applicants' claimed genus.

See also the Court's decision in *In re Baird*, 29 USPQ2d 1550 (Fed. Cir. 1994). In that case, the Court noted that the prior art genus of diphenol compounds for use in developer compositions encompassed bisphenol A, which was used as part of a claimed toner composition. However, the Court held that this generic disclosure did not render obvious the particular claimed embodiment, after comparing the structure of bisphenol A with the structures of the specifically disclosed diphenols in the prior art reference.

Compare also the non-precedential opinion issued by the Board in *Ex parte Rozzi,* 63 USPQ2d 1196, (Bd. of Pat. Appls. & Interf. 2002), where the Board, in reversing an obviousness rejection stated:

> The Examiner does not make out a case of obviousness merely by virtue of the fact that the subject matter of a rejected claim is, to use the examiner's words, 'generically' described by the prior art.

In view of the above remarks, it is respectfully submitted that US '741 fails to render obvious applicants' claimed invention. Withdrawal of the rejection is respectfully requested.

Obviousness-type Double Patenting Rejection in view of Kong et al. (US 6,881,741)

Claims 25, 26, 33, 35, 38-42, 45-47, and 50-101 are rejected as allegedly being obvious in view of claims 1-174 Kong et al. (US '741). This rejection is respectfully traversed.

In the rejection, it is argued that the claims are rejected for obviousness-type double patenting for the same reasons as set forth in the rejection under 35 USC 103. The rejection under 103 is based on the disclosure of specific compounds set forth in the specification. However, an obviousness-type double patenting rejection can not rely on disclosure within a specification. Instead, an obviousness-type double patenting rejection must demonstrate that the **claims** of the reference patent or application render obvious the claimed subject matter. The rejection fails to present any rationale as to how the claims of US '741 render obvious applicants' claims.

Furthermore, as discussed above, the compounds cited in the rejection under 103 do

not lead one of ordinary skill in the art to select a compound in accordance with applicant's claimed genus.

Withdrawal of the obviousness-type double patenting rejection is respectfully requested.

Rejection under 35 USC 112, second paragraph

Claims 25, 26, 33, 35, 38-42, 45-47, and 50-66 are rejected as allegedly being indefinite. This rejection is respectfully traversed.

The rejection asserts that the reference to host in the claims is indefinite. It is argued that a host is an entity that is infected and thus an infection of host can not be prevented.

Applicants respectfully submit that one of ordinary skill in the art can readily understand the language of the claim and thus recognize whether a given embodiment falls within the literal scope of the claim. Nothing more is required by the statute. One skilled in the art would recognize that the claims in question are referring to a potential host in the case of the "preventing" aspect of the claimed method.

In any event, to further prosecution, applicants have amended claims 25 and 61 to delete "or preventing." Claim 42 recites a method for inhibiting or reducing the activity of a flaviviridae viral polymerase in a host. The language of this claim is clear and does not contain the alleged indefiniteness asserted by the Examiner. Further, it is noted that claim 47 is a composition claim and claims 50-60 are compound claims. These claims also do not contain the alleged indefiniteness asserted by the Examiner.

In view of the above remarks, withdrawal of the rejection under 35 USC 112, second paragraph, is respectfully requested.

Rejection under 35 USC 112, first paragraph

Claims 40, 41 61, and 63 are rejected under 35 USC 112, first paragraph, as allegedly being non-enabled. This rejection is respectfully traversed.

The Examiner asserts that claims 40 and 61 recite preventing a viral infection. However, claim 40 does not recite preventing an infection. Also, as noted above, claim 61 is amended to delete "or preventing."

Claims 41 and 63 recite methods that involve administering at least one additional agent chosen from interferon α, ribavirin, silybum marianum, interleukine-12, amantadine,

ribozyme, thymosin, N-acetyl cysteine or cyclosporine, all of which are well known chemical entities. The rejection asserts that the specification is not enabling because it does not describe specific dosages, sequence of administration, or site of administration. However, as these entities are well know in the art, one ordinary skill in the art is aware of how such compounds are administered. That which is well known in the art need not be disclosed in the specification. See, e.g., *Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 802F.2d 1544 (Fed. Cir. 1987). A patent disclose need not describe every last detail since the specification speaks to those skilled in the art. See, e.g., *DeGeorge v. Bernier*, 768 F.2d 1318 (Fed. Cir. 1985).

The test for enablement is not whether any experimentation is needed, but whether or not that experimentation is undue. See, *In re Angstadt*, 190 USPQ 214, 219 (CCPA 1976) in which the art involved (catalysis) was acknowledged to be unpredictable. Even a considerable amount of experimentation, or complex experimentation, is permissible if it is routine. See, e.g., *Ex parte Jackson,* 217 USPQ 804, 807 (POBA 1982) and *In re Wands*, 8 USPQ 2d 1400, 1404 (Fed. Cir. 1988). Details such as dosages, sequence of administration, and site of administration can readily be determined by one of ordinary skill in the art using no more than routine experimentation.

All that is required under the 35 USC 112, first paragraph, is objective enablement. An applicants' disclosure is not required to presents in vivo or in vitro test results. See, e.g., *In re Marzocchi et al.*, 169 USPQ 367, 369(CCPA 1971):

> The first paragraph of §112 requires nothing more than objective enablement. How such a teaching is set forth, either by the use of illustrative examples or by broad terminology, is of no importance.

The MPEP also agrees by stating that "compliance with the enablement requirement of 35 U.S.C. 112, first paragraph, does not turn on whether an example is disclosed." See MPEP § 2164.02.

A mere assertion that a specification does not contain a specific example of a combination of agents does not provide a reason for one of ordinary skill in the art to doubt the truth of the statements in the specification relating to enablement. As noted above, MPEP § 2164.02 states that compliance with the enablement requirement of 35 U.S.C. 112, first paragraph, does not turn on whether an example is disclosed. Applicants specification, the

nature of the invention, and the state of the prior art, particularly with regards to known agents, demonstrate that applicants' specification provides more than sufficient guidance to objectively enable one of ordinary skill in the art to make and use the claimed invention using no more than routine experimentation.

In view of the above remarks, withdrawal of the rejection under 35 USC 112, first paragraph, for lack of enablement is respectfully requested.

Rejection under 35 USC 112, first paragraph

Claims 40 and 62 are rejected under 35 USC 112, first paragraph, on grounds of lack of written description and lack of enablement. These rejections are respectfully traversed.

These rejections object to the terms viral serine protease inhibitor, viral polymerase inhibitor, viral helicase inhibitor, immunomudulating agent, antioxidant agent, antibacterial agent, therapeutic vaccine, hepatoprotectant agent and antisense agent. The Examiner argues that the claim reaches through to future material not yet developed. However, the Examiner presents no rationale as to why claims cannot cover such future embodiments.

The argument made by the Examiner would apply to any claim that uses the transition phrase "comprising." If a claim recites a composition comprising A and B, and an individual subsequently develops a compound C, the claim reciting a composition comprising A and B would cover a composition comprising A, B and C, even though C was developed later.

Moreover, applicants claims are clearly distinguished from the "reach through" claims discussed in *University of Rochester v. G. D. Searle & Co.*, 69 USPQ 2d 1886 (Fed. Cir. 2004), cited by the Examiner. In *Rochester*, the claims were directed to methods of inhibiting the activity of a particular gene by a non-steroidal compound that inhibit the activity of that gene product. All that the patent disclosed were assays that could be used to identify whether a compound had the desired inhibitory activity. Thus, the claimed subject matter was reaching through the inventive assays to claim the use of materials that could be discovered based on use of the assays. The method claims were held to lack written description because the patent failed to describe any compound that had the recited activity, nor was there any evidence that such compounds were known. See *Rochester* at 1895.

Conversely, for each of the classes of agents recited in applicants' claims there are known compounds which have the stated activity. For example, one of ordinary skill in the art is well ware of the numerous known antioxidant agents and anti-bacterial agents.

Using the analysis employed in these rejections, if a claim recites "a salt," but the specification does not list any examples of specific compounds as salts, the claim would lack written description and enablement. However, this analysis fails to take into consideration that salts are well known in the chemical arts.

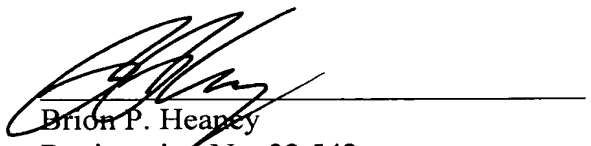
As noted above, that which is well known in the art need not be disclosed in the specification (see, e.g., *Hybritech Inc. v. Monoclonal Antibodies, Inc.*). Compare also *Capon v. Eshar*, 76 USPQ2d 1078, where the claims involved a chimeric gene made from two functionally described gene segments. The Board rejected the claims on grounds that the structure of the gene was not disclosed and thus lacked written description. The Court reversed the Board decision because gene sequences were known that meet the description of each of the two gene segments.

Thus, since one of ordinary skill in the art is well aware of compounds within the agent classes defined in the claims, the written description requirement is satisfied. Furthermore, one of ordinary skill in the art can readily use such known agents and thus make and use the claimed invention with no more than routine experimentation.

In view of the above remarks, withdrawal of the rejections under 35 USC 112, first paragraph, for lack of written and lack of enablement is respectfully requested.

The Commissioner is hereby authorized to charge any fees associated with this response or credit any overpayment to Deposit Account No. 13-3402.

Respectfully submitted,



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